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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,926	09/12/2000	David Salt	2002645-0003	5915

7590 12/19/2003
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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/659,926

Applicant(s)

SALT ET AL.

Examiner

Medina A Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51 is/are allowed.
- 6) ☒ Claim(s) 49, 50 and 52-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/12/03 has been entered.

Applicant's response filed 06/09/03 has been considered.

Claims 49-58 are pending and are examined.

New Matter

Claims 50, 52-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claims 50, 52-54 recite "several thousand fold higher", "7500 fold higher" of more selenium in edible portion of the plant than in the environment the plant is growing, and "several thousand mg/kg dry weight", and "8000 mg/kg dry weight" of selenium accumulated. However, support for the limitations "several thousand fold higher", "7500 fold higher" of more selenium in edible portion of the plant than in the environment the plant is growing, and "several thousand mg/kg dry weight", and "8000 mg/kg dry weight cannot be found in the specification or in the claims as

Art Unit: 1638

originally filed. The chart on page 12 or 13 does not provide sufficient support for these limitations. Therefore, these limitations are considered to be new matter. Applicant is requested to delete the New Matter in response to this rejection.

Claim Objections

Claims 49-58 are objected to because the claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite recite a "method comprising" . The claims lack preamble; a method for what? Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-50 and 52-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of accumulating Se concentration of up to 400 ppm or 2500mg/kg of dry weight in edible Brassicacea plant, does not reasonably provide enablement for a method that allows accumulation of Se of several thousand fold higher or several thousand mg/kg dry weight. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or use the invention commensurate in scope with these claims.

Art Unit: 1638

1. Applicant broadly claims a method comprising growing an edible Brassicacea plant in an environment containing selenium under conditions that allow the plant to accumulate Se, and harvesting the plant after it has accumulated Se concentration that is several thousand, including 7500, fold higher than that of the environment. The claimed method also encompasses accumulation of Se concentration of at least several thousand, including 8000, mg/kg dry weight in specific Brassica plants.

Applicant teaches a method of accumulating Se in *Brassica juncea* by growing the plants in hydroponics media treated with various concentrations of Se in the form of Na₂SeO₄. Applicant also teaches analyzing harvested plant shoots for Se concentration. Applicant further teaches that a maximum concentration of 2,500 mg/kg (0.25% on a dry weight basis) was achieved at 20 mg treatment level and that further increase in Se treatment did not increase the concentration of Se accumulated into plant shoots. (Examples 1 and 6, and Table 2). Applicant teaches that about 20% of the Se accumulated in the plant was Se-methylselenocysteine. Applicant also teaches that about 85% of the Se accumulated in the plant was water soluble (Figure 5).

Applicant has not provided guidance for a method that allows accumulation of Se concentration of at least several thousand or 8000 mg/kg or several thousand fold higher in exemplified or non-exemplified Brassicacea plant, as claimed in claims 50, 52-54. On page 16, lines 1-3, of the specification Applicant states that accumulator and non accumulator plants differ in their capacity to synthesize this nontoxic dead end Se metabolite. However, Applicant has provided no guidance with respect to how to identify

Art Unit: 1638

Brassicacea plant species having the capacity to synthesize such nontoxic dead end Se metabolite.

Banuelos et al (Journal of Environmental Quality, 19:4, pp. 772-777, 1990(U)) discloses studies on the accumulation of selenium in plants. On page 772, column 1, first full paragraph, Banuelos discusses Se hyperaccumulators as follows: "(t)he Se-accumulators are unique plant species because they possess the ability to extract and/or accumulate thousands of milligrams per kilogram of Se (mg/kg, Se dry wt) from soils that contain only several mg/kg". Banuelos reference further states "Selenium uptake by plants is related to other factors.... besides plant species, i.e., form of Se in the soil, presence of other ions in the soil solution, i.e., SO₄..." (paragraph bridging pages 772 and 773). Applicant has provided no guidance with respect to how to identify Brassicacea plant species having Se hyper accumulating ability, and factors other than plant species that influence hyperaccumulation of Se in plants. In the absence of such guidance, one skilled in the art would have to test all Brassicacea plants for their ability to hyperaccumulate Se from various growth mediums including various types of soils. These tests are considered undue and excessive.

Salt et al (Biotechnology, vol. 13, pp. 468-474, 1995(V)) teaches that the ability of a plant to accumulate heavy metals is a genotype dependent and varies greatly between species and between cultivars within the species (page 469, column 2, Phytoextraction). Therefore, absent any specific guidance on how to identify or select a suitable genotype, one skilled in the art would not be able to use any edible

Art Unit: 1638

Brassicaceae plant to accumulate several thousand fold higher or several thousand mg/kg of Se its edible portions, without undue experimentation.

Therefore, given the lack of guidance in Applicants' specification regarding other Brassicaceae plant having the claimed metal accumulating property, the lack of guidance regarding how to select a suitable genotype that can be used in Applicant's method, and the state of the art, the claimed invention is not enabled throughout the broad scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49 and 55-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Banuelos et al (Journal of environmental quality, 1993, vol. 22, no. 4, pp. 786-792 (W)).

The claims are drawn to a method comprising growing an edible Brassicacea plant edible plant in an environment that contains Se under conditions that allow the plant to accumulate Se concentration higher than that in the environment.

Banuelos et al teach a method of accumulating Se in Brassica juncea by growing said plants in a soil containing Se concentration of from 0.1 to 1.2 mg/kg. After several weeks of treatment, plants were harvested and analyzed for Se content. Banuelos teaches that Se concentration in the harvested shoot was more than 1 mg/kg dry matter. The soil Se concentration was reduced by 48% (see at least page 786,

Art Unit: 1638

Abstract). The 20% of the accumulated Se in the form of Se-methylselenocysteine and the 85% water-soluble are inherent properties, since Se is accumulated in a plant.

Remarks

Claims 50-54 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method that allows accumulating of Se in edible portions of a Brassicaceae plant at a concentration of several thousand, including 8000 mg/kg or Se concentration that is several fold higher than that of the growing environment.

Claim 51 is allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina a. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Thursday from 9:00AM to 6:00 P.M. and every other Friday from 9:00-5:30P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 and (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications. Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

12/12/03

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